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EXAMINER	
SCHELL, LAURA C	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,16-27 and 29-37* is/are pending in the application.

4a) Of the above claim(s) *3,24 and 29-37* is/are withdrawn from consideration.

5)☒ Claim(s) *9-12,16-23,26 and 27* is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs 49 and 50) for slidable use with a guidewire (guidewire is 21; the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition. Nevertheless, Griffin discloses all the limitations of the guidewire (Fig. 6a, 29; paragraph [0187] discloses that the guidewire has a stop on it)), the medical device comprising: an elongate tubular member (Figs. 49 and 50,210) having a proximal end (near 2) and a distal end (near 31).with a guidewire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202)

defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongate tubular member, the tip having a first portion having a distal taper (the first portion is. being interpreted as the portion between where the tip begins (at the end of 13) and extending until the beginning of 202, wherein there is clearly a distal taper in this first portion) and a radially inextensible ring distal of the first portion (202 is clearly distal of the first portion as interpreted by the examiner above; also see paragraphs [0266], [0267] and [0303]) wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length) and wherein the tip is configured to deform when the radially inextensible ring contacts the distal stop (Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Therefore any impact with the stop would cause some degree of deformation, as Griffin discloses that the body of the tip is deformable, and a radially inextensible ring is needed as a stop. Please note that applicant's amendment does not specify what type of deformation, to what degree the tip is deformed or how the tip deforms, therefore Griffin meets the functional language amendment to the claim.).

In reference to claim 2, Griffin discloses that a therapeutic device (Fig. 6b, balloon 26) is disposed on the distal portion of the elongate tubular member.

In reference to claim 4, Griffin discloses that the first portion is softer and more flexible than a proximal portion of the medical device (Figs. 49 and 50 disclose that a hypotube (201) is used in the proximal portion of the medical device to stiffen it. Paragraphs [0266], [0267] and [0303] disclose that the first portion is a soft polymeric portion).

In reference to claim 5, Griffin discloses that the ring (202) is the distal most portion of the tip (Figs. 49 and 50).

In reference to claim 6, Griffin discloses that the medical device is an angioplasty device (paragraph [0182]).

In reference to claim 7, Griffin discloses that the medical device is an intravascular filter (paragraph [0182]).

In reference to claim 8, Griffin discloses that the medical device is an intravascular guide catheter (paragraph [0070]).

Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs. 49 and 50), comprising: an elongate catheter (Figs. 49 and 50,210) having a proximal end (near 2), a distal end (near 31), and a lumen (7) extending therethrough; and a tip (generally designated by reference number 31) defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongated catheter, the tip extending distally of the distal end of the catheter (the distal end of the catheter is near 5), the tip comprising a soft body portion (the soft body portion is being interpreted as the portion

between where 13 ends and the beginning of the ring member 202) and a rigid ring (202) distal of the soft body portion (as defined above, the soft body portion extends between the end of 13 and the beginning of 202. Since Applicant has used the word "comprising" to describe what the tip is made of, the tip can be made of more portions/elements other than just the soft body portion and the rigid ring, as "comprising" is considered more open-ended than "composed of". Therefore, while the rigid ring 202 may be surrounded by some soft material, it is still distal of the soft body portion, wherein the "soft body portion" is defined as being between the end of 13 and the beginning of 202.), wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length) and wherein the soft body portion is configured to elastically deform in response to the rigid ring contacting a distal guidewire stop (Figs. 46 and 47 as well as paragraph [0302] and Figs. 37-39 disclose that the distal end of the catheter is made of flexible material, designed to deform upon compression and contact. Furthermore, paragraph [0303] discloses that the radially inextensible ring acts as a stop when contacting the filter. Therefore any impact with the stop would cause some degree of deformation, as Griffin discloses that the body of the tip is deformable, and a radially inextensible ring is needed as a stop. Please note that applicant's amendment does not specify what type of deformation, to what degree the tip is deformed or how the tip deforms, therefore Griffin meets the functional language amendment to the claim.).

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita (US Patent No. 5,989,208). Nita discloses a medical device (Fig. 3) for slidable use with a guidewire (col. 9, lines 38-40; the examiner would like to point out that the Applicant has not positively recited the structure of the guidewire, as the guide wire is "for slidable use" with a medical device, and appears in the preamble which therefore means that the device that is positively claimed by Applicant (the medical device) only has to be capable of being used with the medical device in a slidable condition), the medical device comprising: an elongate tubular member (12b) having a proximal end (near 12b) and a distal end (near 88) with a guide wire receiving lumen (80) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (Fig. 3); and a tip (the tip is being defined as the portion of the tip that is to the right of the vertical arrows near 34b, perhaps better defined as the distal portion of the catheter beginning at 34b, specifically its proximal end begins at the beginning of 34b and its distal end is at the opening of 80 near 88) defining an annular wall disposed at the distal end of the elongate tubular member, the tip having a first portion having a distal taper (any portion of the tip to the right of portion 34b has a distal taper. The examiner is interpreting the first portion as ending at the point 74b, as Applicant has not defined any dimensions for defining the first portion) and a radially inextensible ring distal of the first portion (the portion of 34c that is being interpreted as the radially inextensible ring is the portion to the right of 74b leading up to the distal end of the tip. Please note that Applicant has not required in the claim language that radially inextensible ring be a separate entity form the first portion of

the tip, and therefore the portion that the examiner is interpreting as the ring meets the requirements of the claims as it is a ring in cross section and col. 6, lines 33-52 disclose that the tip is made of rigid material, therefore any ring portion of the tip is also rigid), wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (Fig. 3 discloses that the portion of the tip that decreases in radius, starting at the right end of 34b, also decreases in thickness. It can also be seen that the portion that decreases is larger than the remaining portion of the tip, and therefore the majority of the length of the tip has a thickness that decreases distally) and wherein the tip is configured to deform when the radially inextensible ring contacts the distal stop (as defined above, the tip portion includes anything to the right of the vertical arrows near 34b. Therefore the tip also includes a portion of the coils 40, and as col. 15, lines 24-26 disclose, the coils provide the distal tip of the catheter with flexibility, therefore when the ring contacts the stop or any other object, the tip/coils will deform to some degree because of the nature of the coils and the flexibility they impart to the tip. Please note that applicant's amendment does not specify what type of deformation, to what degree the tip is deformed or how the tip deforms, therefore Nita meets the functional language amendment to the claim.).

In reference to claim 2, Nita discloses a therapeutic device disposed on a distal portion of the elongate tubular member, the tip disposed distal of the therapeutic device (Fig. 8 discloses an embodiment of the catheter which includes a balloon (150) as a therapeutic device).

In reference to claim 3, Nita discloses that the first portion is softer and more flexible than a proximal portion of the medical device (Fig. 3).

In reference to claim 4, Nita discloses that the ring is the distal most portion of the tip (as described above, the ring is being defined as the distal most cross section of the tip, which is a ring in shape).

In reference to claims 6-8, Nita discloses that the device can be an angioplasty device, intravascular filter or intravascular guide catheter (Figs. 3, 8 and 9).

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Nita (US Patent No. 5,989,208). Nita discloses a medical device (Fig. 3), comprising: an elongate catheter (12b) having a proximal end (near 12b), a distal end (near 16b), and a lumen extending therethrough (80); and a tip (the tip is being defined as the portion of the tip that is to the right of the vertical arrows near 34b, perhaps better defined as the distal portion of the catheter beginning at 34b, specifically its proximal end begins at the beginning of 34b and its distal end is at the opening of 80 near 88) defining an annular wall disposed at the distal end of the elongate catheter, the tip extending distally of the distal end of the catheter (Fig. 3), the tip comprising a soft body portion (portion 40 is considered the soft body portion) and a rigid ring distal of the soft body portion (the portion of 34c that is being interpreted as the radially inextensible ring is the portion to the right of 74b leading up to the distal end of the tip. Please note that Applicant has not required in the claim language that radially inextensible ring be a separate entity

form the first portion of the tip, and therefore the portion that the examiner is interpreting as the ring meets the requirements of the claims as it is a ring in cross section and col. 6, lines 33-52 disclose that the tip is made of rigid material, therefore any ring portion of the tip is also rigid), wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (Fig. 3 discloses that the portion of the tip that decreases in radius, starting at the right end of 34b, also decreases in thickness. It can also be seen that the portion that decreases is larger than the remaining portion of the tip, and therefore the majority of the length of the tip has a thickness that decreases distally) and wherein the soft body portion is configured to elastically deform in response to the rigid ring contacting a distal guidewire stop (as defined above, the tip portion includes anything to the right of the vertical arrows near 34b. Therefore the tip also includes a portion of the coils 40, and as col. 15, lines 24-26 disclose, the coils provide the distal tip of the catheter with flexibility, therefore when the ring contacts the stop or any other object, the tip/coils will deform to some degree because of the nature of the coils and the flexibility they impart to the tip. Please note that applicant's amendment does not specify what type of deformation, to what degree the tip is deformed or how the tip deforms, therefore Nita meets the functional language amendment to the claim.).

Allowable Subject Matter

Claims 9-12, 16, 17 and 19-23 are allowed. The subject matter of the independent claims which render the claims allowable which could not be found and

was not obvious over the prior art was the tip comprising an amorphous polymer and the radially inextensible ring comprising a locally crystalline section thereof.

Response to Arguments

Applicant's arguments filed 7/26/2007 have been fully considered but they are not persuasive. Applicant's arguments that the Griffin reference does not specifically mention that the tip would deform if it came in contact with the distal stop on the guidewire is not persuasive, as applicant's amendment is drawn toward functional language. As described above, the tip is deformable upon contact with other objects and Applicant's amendment is broad as it does not specify how much deformation there is, how the tip specifically deforms, or other specifics like that. Griffin discloses that the tip is soft and deformable, and any force on the tip is going to cause some degree of deformation of the tip. However, since Applicant has not specified how much deformation takes place or what kind, Griffin still anticipates the claims.

In addition, the examiner has also brought in another reference (Nita) which also anticipates claims 1-4, 6-8 and 25.

Applicant's arguments, see pages 9 and 10, filed 7/26/2007, with respect to the Van Tassel reference have been fully considered and are persuasive. The rejection of claims 9-12, 16, 17 and 19-23 has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER